



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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Division of Public Health

October 6, 2021

To: North Carolina Local Health Departments

From: Zack Moore, MD, MPH, State Epidemiologist

Re: Guidance for Local Health Departments on Use of At-Home Tests for SARS-CoV-2

Types of Home Tests

Two home testing options have been authorized by FDA for the detection of SARS-CoV-2:

- **At-home collection devices** permit an individual to collect a specimen at home and ship it to a CLIA-certified laboratory for analysis. Results for at-home collections are reported to the individual, the individual's healthcare provider (if ordered by a provider), and public health authorities. Currently, the FDA has authorized many at-home devices for the collection of nasal swabs or oral fluids. To see a current list of FDA authorized at-home collection devices, please visit the FDA's [Emergency Use Authorization for Molecular Diagnostic Tests website](#) and enter the search term "home collect" including quotes.
- **At-home test devices** permit an individual to test and obtain a result for a self-collected specimen at home. Currently, the FDA has authorized both molecular and antigen-based at-home devices that use nasal swab or anterior nares specimen. Some at-home tests require a prescription from a healthcare provider while others are authorized for over-the-counter use. In addition, some at-home test devices require a smartphone to perform the test or obtain results. To see a current list of FDA authorized at-home collection devices, please visit the FDA's [Emergency Use Authorization for Molecular Diagnostic Tests](#) and [Antigen Diagnostic Tests](#) websites and enter the search term "home test" including quotes. **This guidance focuses on at-home test devices.**

Considerations for Use of At-Home Test Devices

Results of at-home COVID-19 tests may not be appropriate or permitted for use in certain situations where documentation of test results is required, such as prior to air travel, before a medical procedure, or to meet requirements of employer-based screening programs. Where

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documentation of test results is required, individuals should consult the requesting entity to find out which tests are acceptable.

In order to facilitate consistent reporting of results and reduce the potential for incomplete or inaccurate data entry by users, NCDHHS recommends that at-home test devices should not be routinely incorporated into planning and implementation of screening or diagnostic testing programs in schools, congregate living facilities, or other settings of public health significance.

In general, results from laboratory tests (i.e., those performed under a CLIA certificate or certificate of waiver) are preferred in situations where results could have significant public health consequences – e.g., for long-term care facilities, prisons and jails, schools, homeless shelters, etc. Persons with positive results from an at home test results can be referred to their provider or the [NCDHHS Find My Testing Place](#) page if confirmatory testing is needed. However, confirmatory testing should not delay appropriate public health actions.

In situations where testing resources are limited or other results are not available, local health departments and schools can choose to accept results of at-home tests to inform public health actions. Some specific examples are listed below.

- Testing of symptomatic individuals to allow return to school when other criteria have been met – i.e., it has been at least 24 hours since the person had a fever (without using fever reducing medicine) and they have felt well for at least 24 hours.
- Use of positive results from at-home tests to identify, define and report an outbreak or cluster.
- Use of positive results from at-home tests to initiate contact tracing, quarantine of contacts, and other public health actions in congregate living settings, schools, or other settings of public health significance.
- Testing to meet the criteria to end quarantine on day 7 after exposure in settings/jurisdictions where shortened quarantine options are being considered.

This list is not comprehensive; local health departments can contact the Communicable Disease Branch epidemiologist on call if they have questions about whether at-home test results should be accepted in other specific situations.

Reporting At-Home Test Results

For at-home tests ordered by a healthcare provider, persons who test positive should immediately report the result to that provider. Healthcare providers are responsible for reporting all results to public health for tests that they order. The most current reporting requirements and methods of reporting of COVID-19 diagnostic tests – including the [NC Administrative Code Rule](#) and the associated guidance – are available on the [DHHS health care guidance page](#).

Individuals are not required to report results of at-home tests to their local health department.

Discordant Test Results

In the case of discordant test results between multiple tests, the [CDC Antigen Testing Algorithm](#) should be followed.

Steps for Entering At-Home Tests in NCCOVID

Negative at-home test results should not be routinely entered into NC COVID. However, positive or negative results of at-home test may be entered into NC COVID at the discretion of the local health department in situations where these results are being used to inform or facilitate public health actions. Positive at-home test results entered into NC COVID will flow to CCTO to facilitate automated notification.

Tests should be entered based on the type of test performed. Under the laboratory test type please select

- For ordering facility – select **“No Ordering Facility – At HOME test”**
- For Lab facility – select **“No Lab Facility – At HOME test”**

In accordance with the current [national surveillance case definition](#) for COVID-19, cases with positive results should be classified as “suspect”. Suspect cases are not included in public counts on the [NCDHHS data dashboard](#) or the [CDC COVID Data Tracker](#) site. Cases with only negative at home results should be classified as does not meet criteria.

Steps for Handling At-Home Tests for Contacts and Entering At-Home Tests in CCTO

Contacts testing positive using an at-home test during the quarantine period should be closed out with the Final Monitoring Outcome of “Contact Tested Positive During Monitoring.” The contact should be entered as a case in NC COVID with a classification of suspect, so that the record will flow to CCTO as a case record for follow-up contact tracing.